

REMARKS

This Amendment is being filed along with a Request for Continued Examination (RCE) to place the application in condition for allowance.

In the Final Office Action mailed June 16, 2005, the Examiner objected to the specification; objected to claims 28-43 based on 35 U.S.C. § 112, ¶ 6; rejected claims 13-15, 19-24, 26, 28-30, 34, 35, 38-40, 42, and 43 under 35 U.S.C. § 112, ¶ 1, ; rejected claim 27 under 35 U.S.C. § 112, ¶ 2; and rejected claims 13-43 under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,866,015 to Krämer.

Claims 13-43 are pending in this application. By this Amendment, claims 13-43 are cancelled without prejudice and claims 44-49 are added to define additional features of Applicants' invention. Prompt consideration of this Amendment and allowance of the application are earnestly requested.

New claim 44 recites, among other things, a method for determining blood recirculation. The method of new claim 44 comprises the steps of, for example, "inducing a succession of variations of value of a blood parameter in the blood flowing in the return line, each variation comprising an increase and a decrease of said blood parameter value around an average value or around a predetermined profile," "measuring, for each variation, at least one value of said blood parameter of the blood flowing in the withdrawal line," and "determining a blood recirculation value in a vascular access of the patient between the return line and the withdrawal line, as a function of said blood parameter values measured for at least one variation and for temporally preceding variations of value of the blood parameter in the blood flowing in the return

line.” (Emphasis added.) Support for new claim 7, may be found, for example, on page 9, lines 23-38 and page 13, lines 3-12.

Applicants respectfully traverse the Examiner’s objections to the specification and claims 28-43; the rejections of claims 13-15, 19-26, 28-30, 34, 35, 38-40, 42, and 43 under 35 U.S.C. § 112, ¶ 1; and the rejection of claim 27 under 35 U.S.C. § 112, ¶ 2. Applicants respectfully note that these objections and rejections are moot in light of the cancellation of claims 13-43.

Applicants also respectfully traverse the Examiner’s rejections of claims 13-43 under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative under 35 U.S.C. § 103(a) as being obvious over Krämer, and submit that these rejections are also moot in light of Applicants’ rejections of claims 13-43.

Insofar as the Examiner’s rejections under 35 U.S.C. §§ 102(e) and 103(a) are relevant to new claims 44-49, however, Applicants respectfully submit that new claim 44, for example, is neither anticipated by, nor obvious over Krämer at least because Krämer does not teach or suggest the claimed method including the step of “inducing a succession of variations of value of a blood parameter in the blood flowing in the return line, each variation comprising an increase and a decrease of said parameter value around an average value or around a predetermined profile.” (Emphasis added.) Nor does Krämer teach or suggest a method including the step of “determining a blood recirculation value in a vascular access of the patient between the return line and the withdrawal line, as a function of said blood parameter values measured for at least one variation and for temporally preceding variations of value of the blood parameter in the blood flowing in the return line.” (Emphasis added.)

The Examiner asserts that Krämer teaches a method for determining hemodynamic parameters during extracorporeal hemotherapy wherein “a blood parameter, such as a concentration of a blood constituent, flow or hematocrit, is measured using well-known measuring sensors.” (Office Action at 7.) The Examiner also asserts that “Krämer substantially discloses the invention as claimed,” however, the Examiner concedes that Krämer does not disclose that “there are disturbances induced [by] a variation of, or a succession of changes, in the concentration of hemoglobin in the blood. *Id.* The Examiner further asserts, however, that “Krämer inherently teaches taking multiple measurements of a blood parameter, which inherently includes at least one or a succession of variations of hemoglobin concentration as said parameter,” and states that “[i]f Applicant disagrees with the Examiner’s position, then it would have been obvious to one having ordinary skill in the art to choose to make measurements of hemoglobin concentration variation to be used in the calculation.” (Office Action at 8.) Applicants respectfully submit that the Examiner’s assertions are misplaced.

In determining a fistula flow, Krämer teaches to slowly increase extracorporeal blood flow “from a predetermined lower limiting value ... to an upper limiting value.” (Col. 8, lines 55-57.) Krämer further discloses that “[t]he temperature T_A of the blood in the arterial branch 20 of the extracorporeal circuit 9 is measured while the blood flow increases using arterial measuring device 24.” (Col. 8, lines 62-65.) Krämer does not teach, however, “inducing a succession of variations of value of a blood parameter” (*i.e.*, blood flow) in the return line such that each variation comprises “an increase and a decrease of said blood parameter,” as recited in new claim 44. (Emphasis added.) Further, as noted above, Krämer teaches determining fistula flow as a function of

increasing arterial blood flow values (see col. 8, lines 53-67) measured during a single step without using values measured in preceding steps, and does not teach determining blood recirculation “as a function of said blood parameter values measured for a variation and for temporally preceding variations of value of the blood parameter in the blood flowing in the return line,” wherein each variation comprises “an increase and a decrease” of the blood parameter, as recited in new claim 44.

Krämer further teaches a method wherein a change in a first blood parameter (e.g., blood flow) is induced both in the return line and the withdrawal line while a second blood parameter (e.g., blood temperature) is kept constant in the return line and is measured in the withdrawal line. (Col. 4, lines 33-58.) Krämer, however, fails to disclose or suggest a method for determining blood recirculation wherein there are “successive variations of value of a blood parameter in the blood flowing in the return line” and the same blood parameter is “measur[ed], for each of the variations.....[in the] blood flowing in the withdrawal line,” as recited in new claim 44.

In light of the above-described deficiencies of Krämer, new claim 44 is allowable over the applied reference, and new claims 45-49 are allowable at least due to their dependence from new claim 44.

Further, with respect to new claims 44-49, Applicants note that the Examiner contends that “it would have been obvious to one having ordinary skill in the art to choose to make measurements of hemoglobin concentration variation to be used in the calculation as the desired parameter based on the design of a patient’s treatment.” (Office Action at 8). The Examiner, however, fails to cite any supporting language in

Krämer for this assertion. Accordingly, Applicants request that this rejection be withdrawn and new claims 44-49 allowed, for at least the above reasons.

In view of the above amendments, Applicants assert that the entire application is now in condition for allowance. A timely notice of allowance is earnestly requested.

The Examiner is invited to telephone the undersigned at (202) 408-4387, should the Examiner foresee any impediment to allowance.


The Office Action may contain statements or characterizations with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 15, 2005

By: 
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